K120443

MAY 2 2 2012

5. 510(k) SUMMARY

February 13, 2012

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

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DEVICE NAME:

Trade name: Neutral Luer Activated Device and Extension Sets with Neutral Luer Activated Device

Code	Product
7N8399	Neutral Luer Activated Device ,Power Injectable (325 psi, 2241 kPa),
7N8371	Neutral Luer Activated Device Non-DEHP Y-Type Microbore Catheter Extension Set
7N8377	Neutral Luer Activated Device Non-DEHP Y-Type Standard Bore Catheter Extension Set
7N8378	Neutral Luer Activated Device Non-DEHP Standard Bore Catheter Extension Set
7N8300	Neutral Luer Activated Device Non-DEHP Microbore Catheter Extension Set, Power Injectable (325 psi, 2241 kPa),

Common name: IV Administration Set

Classification name: IV Administration Set (21 CFR 880.5440, Product Code FPA)

PREDICATE DEVICE:

Three predicate devices are cited in support of the substantial equivalence determination:

- Baxter Healthcare Solution Administration Sets with Capped Luer Activated Valve, K003225 cleared on October 19, 2000
- Pressure Rated Extension Sets, K083472 cleared on November 18, 2008
- InVision Plus Injection Port Systems, K991653, cleared June 24, 1999

DESCRIPTION OF THE DEVICE:

The Neutral Luer Activated Device (LAD) and Extension Sets with Neutral Luer Activated Device are single use disposable devices intended for use with a vascular access device for continuous or intermittent fluid administration or withdrawal of fluids. The device is an in-line access site and can be connected to male Luer adapters (e.g., syringes or sets) to allow needleless access to the fluid or vascular path and is designed to be easy to swab.

A saline flush of 10 mL is able to clear the Neutral LAD of blood after sampling blood through the device. The Neutral LAD is clear and allows the clinician to view the fluid path of the device.

The Neutral LAD has a low priming volume (0.08 mL) that allows medication to be flushed from the device with small amounts of fluid and is the maximum amount of medication that could potentially remain in the device when administered to a patient prior to flushing. A LAD with a low priming/residual volume is favored for pediatric patients or patients requiring fluid restriction.

The device is a neutral fluid displacement LAD and does not require a specific clamping sequence in order to be used safely. This neutral displacement design has the added benefit of helping to reduce the occurrence of thrombotic catheter occlusions by limiting the reflux of blood into the catheter.[1,2]

[1] Hadaway, Lynn C., "Reopen the Pipeline for IV Therapy," *Nursing2005*, Volume 35, Number 8, 54-62.
[2] *Infusion Nursing: An Evidence-Based Approach*, ed. Mary Alexander, et al., (St. Louis: Saunders Elsevier, Inc. 2010), 495-515.

The Neutral LAD may be used with low pressure power injectors having a maximum pressure of 325 psi (2241 kPa) and a maximum flow rate of 10 mL/s.

STATEMENT OF INTENDED USE:

The Baxter Neutral Luer Activated Device is intended for single patient use with a vascular access device for the administration of drugs and solutions without needles, thus eliminating the potential for needle-stick injuries during use. This device is an in-line injection site which can be connected to standard male Luer adapters (e.g., syringes or sets) for the continuous or intermittent fluid administration or the withdrawal of fluids. This device may be used with low pressure power injectors having a maximum pressure of 325 psi (2241 kPa) and a maximum flow rate of 10 mL/s.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The Neutral Luer Activated Device and Extension sets with the Neutral Luer Activated Device are substantially equivalent to the predicate devices listed above. The Neutral LAD is a neutral fluid displacement device that does not require a specific clamping technique to work safely and effectively for continuous or intermittent fluid delivery. The Neutral LAD is designed to be easy to swab and is appropriate for use with power injectors having a maximum pressure of 325 psi (2241 kPa) and a maximum flow rate of 10 mL/s. The product is sterile and non-pyrogenic. Testing supports use of the device for 7 days and/or 200 actuations.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. This device met all the acceptance criteria for all functional, biocompatibility, microbial ingress, sterility and ease of use requirements and the data support that the device is appropriately designed for its intended use.

CONCLUSION:

The Neutral Luer Activated Device (LAD) and Extension Sets with the Neutral Luer Activated Device are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 22 2012

Ms. Nanette Hedden
Associate Director, Global Regulatory Affairs
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Illinois 60085

Re: K120443
Trade/Device Name: Neutral Luer Activated Device and Extension Sets with Neutral Luer Activated Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Set, Administration, Intravenous
Regulatory Class: II
Product Code: FPA
Dated: April 27, 2012
Received: May 1, 2012

Dear Ms. Hedden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Neutral Luer Activated Device and Extension Sets with Neutral Luer Activated Device

Indications for Use:

The Baxter Neutral Luer Activated Device is intended for single patient use with a vascular access device for the administration of drugs and solutions without needles, thus eliminating the potential for needle-stick injuries during use. This device is an in-line injection site which can be connected to standard male Luer adapters (e.g., syringes or sets) for the continuous or intermittent fluid administration or the withdrawal of fluids. This device may be used with low pressure power injectors having a maximum pressure of 325 psi (2241 kPa) and a maximum flow rate of 10 mL/s.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/22/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120443
